light emitter, a bispectral emitter, a dual spectral emitter, a photoemitter, a photodiode, a semiconductor die, or the like, and the detector may include a photodiode, a photoelectric receiver, a photodetector such as a broadband photodetector, a semiconductor die, or the like.

[00117] The light source and detector may the same as or in addition to the above described elements used for RBC characterization. Examples of commercially available pulse characterization elements, e.g., Doppler flowmeters, adaptable for use with the present invention to determine flow characterization include, but are not limited to, flowmeter models LD-5000 and LD-6000 manufactured by Medpacific of Seattle, WA; flowmeter models PF1, and models PF2 and PF3 manufactured by Perimed of Stockholm, Sweden.

[00118] The pulse characterization element may be operatively may be associated with a microprocessor under the control of a software program that is capable of processing signal from the site and determining the pulse or determining a magnitude associated with the pulse, or a statistically relevant value thereof, of the site based upon the measured intensities of the reflected light and may also perform the steps necessary to compare such a pulse value to a predetermined value or to pulse values of various tested sites.

B. Hemoglobin Characterization Element

[00119] In certain embodiments of the subject invention, the sample type characterization element includes a hemoglobin characterization element capable of determining the characteristic of hemoglobin of a site. In particular, the hemoglobin characterization element is configured to determine the total hemoglobin level of the site and/or determine the amount of oxygenated hemoglobin to deoxygenated hemoglobin or the HbO/Hb ratio.

[00120] The hemoglobin characterization element is typically an optics element, where such an optics element contains (1) at least one light source such as at least one of the following: a light emitting diode (LED), a light emitter, a bispectral emitter, a dual spectral emitter, a photoemitter, a photodiode, a semiconductor die, laser, or the like, and (2) at least one detector capable of measuring light absorbed by the site, *i.e.*, intercepting light transmitted through or reflected from a surface upon which the light source is

focused, and which may also capable of converting such light into measurable electrical signals, *e.g.,* voltage, current, *etc.*), where suitable detectors include, but are not limited to, at least one of the following: a photodiode, a photoelectric receiver, a photodetector, a semiconductor die, or the like. As noted above, light sources and detectors are commonly known in the art, where examples of suitable light sources and detectors suitable for use with the present invention include those disclosed in U.S. Patent Nos. 6,241,680 and 6,233,266, the disclosures of which are herein incorporated by reference.

[00121] Typically, the at least one light source of relatively narrow wavelength distribution, *e.g.*, at least one LED or laser, will be capable of irradiating a prospective sampling site with at least one wavelength, typically at least two wavelengths ranging from about 400-1200 nm. In other words, if one light source is used and more than one wavelength is required, the one light source will be capable of producing or emitting light at more than one wavelength. If more than one light source is used, at least two of such light sources will be capable of transmitting light at different wavelengths either serially or simultaneously with respect to each other. The at least one light source and/or the associated detector(s) may be positioned at or near the proximal end of the housing, *i.e.*, the portion of the housing in close proximity to or in direct contact with the skin of the user. In other words, the light source(s) and/or detector(s) may be located near the proximal orifice of the device; however, the light source(s) and /or detector(s) may be positioned elsewhere in the device as well.

[00122] The hemoglobin characterization element may be operatively associated with a microprocessor under the control of a software program that is capable of processing signal from the site and determining total hemoglobin or the components thereof (oxygenated or deoxygenated Hb) or the HbO/Hb ratio, or a statistically relevant value thereof, of the site based upon the measured absorbances of the light and may also be operatively associated with measurement processing means for performing the steps necessary to compare such hemoglobin values to a predetermined value or to hemoglobin values of various tested sites.

III. Measurement Processing Components

[00123] The device also includes associated electronics for processing the measurements or signals produced by the site flow characterization element and/or the sample type

characterization element and/or may be used to automatically determine the concentration of an analyte in the sample, as described below. For example, in many embodiments the device may also includes a current to voltage converter unit and an analog to digital converter, where such electronics are known in the art.

[00124] Furthermore, the device includes a microprocessor working under the control of a software program, where such a software program contains the entire code necessary for the microprocessor to perform all of the tasks required by the device, *e.g.*, the microprocessor contains all the code necessary for determining the suitability of a sampling site and/or the concentration of an analyte. In other words, the program code of the software instructs the microprocessor to carry out all the steps which are necessary for it to determine one or more of the site's functions, such as the flow characteristics of the site, and/or the sample type characteristics, i.e., whether the site include primarily arterial/capillary, venous or interstitial fluid, the appropriateness of the site for a particular test and the concentration of at least one analyte in the sample, among other functions such as automatically activating the device, *etc.*

IV. Skin Piercing Element

[00125] The device may further include at least one skin-piercing element, *e.g.*, a needle or the like, for accessing and withdrawing or collecting the targeted sample fluid. The at least one skin-piercing element may be associated with an actuating mechanism, such as a spring-loaded mechanism, for manually actuating the at least one skin-piercing element towards the skin; however, the at least one skin-piercing element may also be capable of being activated automatically. Representative lancing elements adaptable for use with the present invention include, but are not limited to, those disclosed in U.S. Patent Nos. 4,449,529; 4,892,097; 5,314,441; 5,318,54; 5,366,469; 5,395,388; 5,439,473; 5,454,828 5,540,709, 6,197,040; 6,071,294; 6,045,567 and 6,036,924, the disclosure of which are herein incorporated by reference. Furthermore, the Penlet® brand Blood Samplers manufactured by LifeScan, Inc. are also adaptable for use with the present invention. The at least one skin-piercing element may further include a fluid pathway or channel operatively associated with, *e.g.*, either within, concentric with or adjacent to, the at least one skin-piercing element for transporting fluid accessed by the element.